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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,543	10/04/2001	Benjamin Eithan Reubinoff	14418Z	1839
7590	03/05/2004		EXAMINER	
Scully, Scott, Murphy & presser 400 Garden City Plaza Garden City, NY 11530			CROUCH, DEBORAH	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,543

Applicant(s)

REUBINOFF ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of group IV claims 65-73 is acknowledged. The traversal is on the ground(s) that the requirement according to the MPEP for restriction is that the inventions be found to be both independent and distinct. This is not found persuasive because the MPEP clarifies this by stating that distinct inventions can be separated even if independent (MPEP 802.01, parag. 5). Applicant also argues that some of the groups assigned by the examiner are of the same classification. This is not found persuasive because MPEP states that only when the classification and the field of search are the same is there to be no restriction. In the present situation, there is difference in field of search. Applicant also argues the undue burden and expense of multiple simultaneous prosecutions of the different groups. This is not persuasive as burden and expense of prosecution is not discussed in the MPEP as a reason to withdraw a restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Australia on 3/14/00, 6/11/00 and 6/2/01. It is noted, however, that applicant has not filed a certified copy of these applications as required by 35 U.S.C. 119(b). Further, these priority documents could not be found in parent 08/808,382.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 65-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez-Serrano et al (1995) J. Neurosci. 15, 5668-5680 in view of Svendsen et al (1995)

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Exper. Brain Res. 102, 407-414 and Fricker et al (1999) J. Neurosci. 19, 5990-5005 and further in view of Li et al (1995) Current Biol. 8, 971-974.

Martinez-Serrano teaches the implantation of CNS derived neural progenitor cells transfected with a retrovirus comprising an DNA sequence encoding NGF into a rat having a complete fimbria-fornix lesion prevent significant loss of cholinergic cell (Martinez-Serrano, page 5676, col. 2, parag. 1, lines 1-7 and figure 7). Svendsen teaches the growth of neural progenitor cells in media comprising EGF and B27 dramatically increases the number of dividing progenitor cells in primary cells (page 411, col. 2, parag. 1, lines 8-11). Svendsen also teaches that these cells, in response to EGF, differentiate into neurons, glia and oligodendrocytes (page 411, col. 2, parag. 1, lines 3-7). Fricker et al teaches bFGF is need to support continuous cell proliferation of neural progenitor cells (pages 5991-5992, bridg. sent.). Fricker also teaches that EGF and bFGF act cooperatively in promoting the proliferation of neural progenitor cells (page 6001, col. 2, parag. 1, lines 2-5). Fricker teaches the injection of neural progenitor cells into the ventricular zone develop into neuronal cells (page 6002, col. 2, parag. 1, lines 1-6). Fricker teaches that the neural cells taught can provided an unlimited source of neural cell progenitors for transplantation (page 6003, col. 2, parag. 3, lines 7-10). Li teaches a method of inducing the differentiation of embryonic stem (ES) cells into neural progenitor cells comprising dissociating embryoid bodies (EB's) formed from aggregating ES cells, and culturing the dissociated EB's in media containing retinoic acid and N2 supplement on substrate which supports neural cells (page 971, col. 1, lines 7 to col. 2, line 2). Claim 66 says the neural progenitor cells are injected into the lateral cerebral ventricle. The site of injection in Martinez-Serrano, the septum, is a wall of lateral cerebral ventricle. Thus, injection of neural progenitor cells into the lateral ventricle would deliver cells to the septum.

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Thus at the time of filing, it would have been obvious to the ordinary art to treat a neurodegenerative disorder, such as a complete fimbria-fornix lesion, transplanting into the brain neural progenitor cells transfected to contain a retrovirus comprising a DNA sequence encoding NGF, as taught by Martinez-Serrano, thereby modifying the nervous system and producing a stable graft that contributes to the histogenesis, wherein the neural progenitor cells have been derived by culturing the stem cells in the presence of serum free media comprising B27, EGF and bFGF to obtain a larger number of proliferating neural progenitor cells, as taught by Svendsen and Fricker, where the neural progenitor cells were derived by culturing ES cells in vitro with a differentiation inducing signal under conditions that are not permissive for stem cell renewal, do not kills and/or induces unidirectional differentiation, as taught by Li and. Motivation comes from Martinez-Serrano stating that their methods provides a means to treat brain lesions requiring the generation of neurons or glial cells (page 5679, col. 1, parag. 1, lines 1-10). Svendsen teaching that B27 enables a dramatic increase in the number of dividing neural precursor cells, and Fricker teaching that growth of neural progenitor cells in the presence of both EFG and bFGF act cooperatively to promote the proliferation of such cells (page 6001, col. 2, parag. 1, lines 2-4). Li offers motivation in stating that the development of techniques for producing neural progenitor cells from ES cells would provide a source of cells for transplantation (page 973, col. 2, parag. 1, line 1 to page 974, col. 1, line 1). Thus, at the time of filing, the provides the requisite teaching, suggestion and motivation for the presently claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

March 3, 2004